

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION

MDL NO. 1456
CIVIL ACTION NO.
01-CV-12257-PBS

THIS DOCUMENT RELATES TO ALL CLASS
ACTIONS

Judge Patti B. Saris

**DEFENDANTS' RESPONSE TO NOTICE OF FILING MODIFIED
AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT**

Defendants submit this memorandum to explain that nearly all of the claims in the Amended Master Consolidated Class Action Complaint ("AMCC") must be dismissed for lack of standing.

I. INTRODUCTION

Plaintiffs filed the AMCC on June 12, 2003. According to plaintiffs, they "carefully crafted" (see Plaintiffs' Memorandum In Opposition to Motion to Dismiss, p. 1) the AMCC after a "massive review of each Defendant, its products and its pricing conduct," including consultations "with pharmaceutical industry experts and insiders." Plaintiffs' Separate Memorandum in Opposition to Defendant-Specific Memoranda on Motions to Dismiss, at 4. At the November 21, 2003 hearing, plaintiffs described in detail the meticulous "triage" that purportedly led to the filing of the AMCC. See 11/21/03 Tr. at 19-22.

At the same hearing, defendants pointed out that none of the plan plaintiffs had specifically alleged that they made any Medicare Part B co-payments, and thus the plans lacked both RICO and Article III standing to bring the claims “FOR UNLAWFUL CONDUCT ASSOCIATED WITH MEDICARE PART B COVERED DRUGS” set forth in Count I. See id. at 41-44.^{1/} In addition, defendants pointed out that none of the plan plaintiffs had specifically alleged that they contracted with a particular PBM for reimbursement based on AWP, and thus the plans lacked RICO and Article III standing to bring the claims set forth in Count II. See id. at 44-47.

In response to questioning by the Court, plaintiffs acknowledged that the AMCC did not allege that any of the plan plaintiffs contracted with a PBM based on AWP. See id. at 51-52. The Court stated that the absence of such a contract would be “fatal,” and allowed plaintiffs to amend to make this simple allegation. Id. at 51-52.

On December 5, 2003, plaintiffs filed a “modified” AMCC. Counting the complaints that were filed in various courts around the country before being consolidated in this MDL, this represents plaintiffs’ fourth attempt to plead viable claims and establish that they have standing to bring them. However, even this attempt has failed to cure plaintiffs’ fundamental inability to establish standing. With one exception discussed below, the modified AMCC again fails to allege that the plan plaintiffs made Medicare Part B co-payments, such that they would have standing to bring claims related to Medicare Part B reimbursement. Further, each of the plan plaintiffs persists in refusing to make the simple declarative statement that it contracted with a specific PBM for

^{1/} Defendants also noted that the associational plaintiffs had expressly disclaimed any claim for damages (AMCC ¶¶ 32-36) and thus were not bringing the RICO claims (AMCC ¶¶ 646, 679). See Tr. 11/21/03 at 41-42. Plaintiffs do not dispute this point.

reimbursement based on AWP. More importantly, none of the plan plaintiffs state that they had any relationship with the four PBMs that allegedly joined defendants in the so-called “Manufacturer-PBM Enterprises” and Manufacturer-PBM conspiracies.^{2/} Thus, none of the plaintiffs have pleaded facts sufficient to establish standing to bring claims related to reimbursement through these PBMs.

As discussed more fully below, the discovery that plaintiffs have produced to date reveals why plaintiffs have pleaded so vaguely. The discovery shows that only plaintiff UFCW made any Medicare Part B co-payments. The discovery also shows that the only one of the four identified PBMs with which any plaintiff contracted was Express Scripts, and that only two of the plaintiffs (PFT and Man-U) contracted with Express Scripts during the relevant time period. Consequently, to the extent that the AMCC survives defendants’ substantive motions to dismiss, any Medicare Part B claims must be limited to the drugs for which UFCW made Medicare Part B co-payments, and to the manufacturers of those drugs. Further, the PBM-related claims must be limited to those drugs for which PFT and Man-U made payments through Express Scripts based on AWP, and to the manufacturers of those drugs. The remaining claims must be dismissed for lack of standing.

^{2/} Plaintiffs identify Advance PCS, Caremark Rx, Inc., Express Scripts, Inc. and Medco Health Solutions, Inc. (AMCC ¶ 650) and allege that each defendant formed a separate enterprise with each of these PBMs (e.g. the “Abbott-Advance PCS Enterprise”) (¶ 661) and a separate conspiracy with each of these PBMs (e.g. the “Abbot Manufacturer-PBM Conspiracies”) (¶ 728).

II. ARGUMENT

A. The Modified AMCC Reveals Plaintiffs' Lack of Standing

In order to establish standing, the plaintiff must make out “a ‘case or controversy’ between himself and the defendant within the meaning of Art. III.” Warth v. Seldin, 422 U.S. 490, 498 (1975). If a plaintiff lacks standing, “the court lacks jurisdiction to decide the merits of the underlying case.” Libertad v. Welch, 53 F.3d 428, 436 (1st Cir. 1995) (citing United States v. AVX Corp., 962 F.2d 108, 113 (1st Cir. 1992)). Because Article III standing goes to a court’s jurisdiction, the inquiry remains open at any stage of a litigation. Id. at 435 (citing National Org. for Women v. Scheidler, 510 U.S. 249 (1994)).^{3/} The Article III standing requirement ensures that federal courts exercise jurisdiction only to resolve claims brought by a *specific* plaintiff who seeks redress for a *specific* injury that can be fairly traced to a *specific* defendant. See Libertad, 53 F.3d at 436 (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 559-61 (1992)).^{4/}

In addition to satisfying the Article III standing requirements, a plaintiff asserting a RICO claim “only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the violation.” Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985).

3/ In Libertad, the Court of Appeals for the First Circuit considered a standing issue that defendants raised for the first time at oral argument before that Court. 53 F.3d at 435.

4/ As this Court has previously noted, “under long standing case law, ‘[a] named plaintiff cannot acquire standing to sue by bringing his action on behalf of others who suffered injury which would have afforded them standing had they been named plaintiffs . . . Standing cannot be acquired through the backdoor of a class action’.” In re Pharmaceutical Industry Average Wholesale Price Litigation, 263 F. Supp.2d 172, 193 (D. Mass. 2003).

1. Standing to Bring Medicare Part B Claims

As discussed above, the modified AMCC alleges that only one of the plaintiffs -- UFCW -- made co-payments under Medicare Part B. See modified AMCC ¶ 29.^{5/} Thus, no other plaintiff has standing to bring a claim -- under any theory -- related to Medicare Part B. Accordingly, the AMCC must be dismissed to the extent that it seeks to bring Medicare Part B claims beyond the drugs for which UFCW made Medicare Part B co-payments. This includes the claims set forth in Count I. It also includes the claims set forth in Count IV for violations of state consumer protection statutes, to the extent that this count is intended to cover conduct related to Medicare Part B.

2. Standing to Bring PBM-Related Claims

The AMCC identifies the four largest PBMs (¶¶ 170, 650) and alleges that these PBMs formed RICO enterprises (Count II) and conspiracies (Count IX) with each of the defendants (¶¶ 661, 728). However, plaintiffs still do not allege that they contracted with any of these PBMs. See modified AMCC ¶¶ 26-31.^{6/}

The minimal discovery that plaintiffs have produced to date reveals why they continue to plead in vague terms. According to plaintiffs' discovery:

1. TCBW did not contract with a PBM until July 2003, when it apparently entered into a contract with Caremark, Inc. TCBW has not produced this contract, which was signed after the AMCC was filed in any event.

2. THWF has used General Prescription Programs, Inc. as a PBM, but apparently has not used any of the PBMs identified in the AMCC.

^{5/} UFCW does not identify the drugs for which it made Medicare co-payments. However, the discovery that UFCW has produced suggests that UFCW made such payments for a limited number of drugs.

^{6/} In fact, CMHV and TCBW now acknowledge that they did not directly contract with any PBM during the relevant time period. See modified AMCC ¶¶ 26 (CMHV), 28 (TCBW).

3. PFT signed a contract with Express Scripts, one of the identified PBMs, but not until May 2002. Before then, PFT contracted with other PBMs not identified in the AMCC.

4. Man-U signed a contract with Express Scripts in March 2003. It appears that Man-U may have contracted with Express Scripts before that time, but Man-U has produced no other contracts.

5. UFCW signed an agreement with Express Scripts in June 2003, the same month in which the AMCC was filed. Before that time, UFCW appears to have contracted with a PBM other than those identified in the AMCC.

In sum, plaintiffs' own discovery shows that no plaintiff has standing to claim an injury related to any of the identified PBMs other than Express Scripts. Moreover, it appears that only PFT and Man-U contracted with Express Scripts during the relevant time period, and even then only recently.

This is not a mere technical deficiency. Count II claims that defendants caused injury by forming "enterprises" with each of the four specific PBMs and conducting the affairs of those enterprises through a pattern of racketeering activity, and Count IX claims that defendants caused injury by conspiring with each of the four specific PBMs. A plaintiff that did not contract with any of the identified PBMs cannot claim to have been injured by this activity. A plaintiff cannot claim to have been injured by racketeering activity involving, for example, the "Abbott-Advance PCS Enterprise" if it had no relationship with Advance PCS. Similarly, a plaintiff cannot claim to have been injured by a conspiracy between a manufacturer and a PBM with which the plaintiff had no relationship. To the extent that the AMCC survives defendants' substantive motions to dismiss, it must be limited to (1) those plaintiffs that contracted with Express Scripts, (2)

the time periods of those contracts, (3) the drugs for which these plaintiffs made payment based on AWP pursuant to those contracts, and (4) the manufacturers of those drugs.

This applies to Counts II and IX, as well as the consumer protection claims in Count IV.

B. Scope of Count I

The court allowed plaintiffs to amend the AMCC to establish standing, but cautioned them not to add any new claims or theories. See 11/21/03 Tr. at 22-23, 46. While failing to do what the Court allowed, plaintiffs misused the opportunity given by the Court, changing their theory of the case yet again. Plaintiffs now contend that, despite the plain language of the “carefully crafted” AMCC, Count I was never meant to be limited to Medicare Part B. Rather, plaintiffs assert that their limiting of Count I to the Medicare Part B context was a “typographical error.” See Notice of Filing at 3. Plaintiffs claim that if defense counsel had simply called plaintiffs’ counsel before the argument, plaintiffs “could have cleared this issue up quickly” (Notice of Filing at 3), presumably by pointing out the typographical error.

This claim is belied by plaintiffs’ response when confronted with this issue at the November 21 hearing:

THE COURT: What about his claim in Medicare Part B, there’s no allegation that any of the specific plaintiffs paid for either through co-pays or on their own --

MR. BERMAN: You mean on count one?

THE COURT: In count one.

MR. BERMAN: That’s a new one. I do want to think about it.

11/21/03 Tr. at 54. If the defect in Count I was a typographical error, plaintiffs did not offer this simple, fairly obvious explanation to the Court. Instead, plaintiffs asserted that

On count one, there are five or six individual Medicare Part B plaintiffs who are identified early in the complaint in the associations who, we allege, made these co-payments. So they clearly fit within count one.

Id. at 55. However, none of the individuals are plaintiffs in this case. Further, as discussed above, the associations are not bringing damage claims, and would not have standing to do so. See Libertad, 53 F.3d at 437 (Pro-choice group lacked RICO standing). Thus, plaintiffs' claim of "typographical error" -- and corresponding attempt to expand Count I -- is merely an attempt to avoid the fact that the AMCC did not establish that any plaintiff had standing to bring a Medicare Part B claim.^{7/}

The language and structure of the AMCC also belies plaintiffs' claim of typographical error. A simple glance at the Table of Contents shows the division between the claim that "The Defendant Drug Manufacturers Commit AWP Fraud To Increase Their Market Share For Their Drugs Covered By *Medicare Part B*" and the claim that "The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain the Price of Drugs *Outside of the Medicare Part B Context*." (emphasis added). Consistent with this distinction, Count I of the AMCC deals with claims under Medicare Part B, and Count II deals with claims outside the Medicare Part B context.

As the Court noted, the AMCC already engendered "a major shift in the kinds of claims" at issue in this case. 11/21/03 Tr. at 23. Now, confronted with fundamental deficiencies in their pleadings, plaintiffs try to shift again. Despite their previous statement that it dealt with fraud in the Medicare Part B context, plaintiffs now assert that

^{7/} This is not the first time that plaintiffs have claimed typographical error in response to exposure of a standing problem. When defendants pointed out plaintiffs' lack of Article III standing in the MCC during the January 13, 2003 hearing before this Court, plaintiffs' counsel stated that it was "a drafting error." 1/13/03 Tr. at 73. Rather than correct this "error," plaintiffs dropped the individual plaintiffs from the AMCC.

Count I is intended to and does cover non-PBM transactions for AWPID drugs of which several plaintiffs are class representatives by virtue of purchasers outside the PBM context.

Notice of Filing at 3. However, to accomplish this end, plaintiffs do not simply remove a heading that, as plaintiffs claim, inadvertently survived the previous complaint. Rather, they also seek to re-write ¶ 620, which describes the claim asserted in Count I. The Court should reject this latest expansion of the claims in this case, and should preclude plaintiffs from effectively amending Count I in this manner.

III. CONCLUSION

This case illustrates the confusion that can occur when plaintiffs strive to bring a case that is as big as possible rather than bringing a case that is properly pleaded. After four attempts, plaintiffs no longer deserve the benefit of the doubt. By continuously shifting and expanding their claims through ambiguous pleadings, plaintiffs have expanded this case beyond constitutional bounds and denied the Court the opportunity to efficiently manage this proceeding. Plaintiffs cannot claim that they were injured in the context of Medicare Part B if they made no payments under Medicare Part B. Similarly, plaintiffs cannot claim that they were injured by manufacturers that engaged in RICO enterprises or conspiracies with PBMs with which plaintiffs had no relationship.

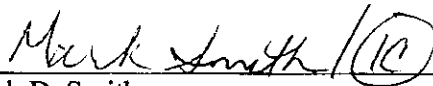
For these reasons, to the extent that this case survives defendants' substantive motions to dismiss, it must be limited as follows: (a) all claims in the AMCC based on Medicare Part B co-payments should be dismissed except with respect to those drugs for which UFCW made such co-payments; and (b) all claims in the AMCC related to payments through PBMs should be dismissed except for drugs on which PFT and Man-U

made payments based on AWP pursuant to contracts with Express Scripts. Any other claims must be dismissed for lack of standing.

Respectfully submitted,

ON BEHALF OF ALL DEFENDANTS

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Judge Patti B. Saris

CERTIFICATE OF SERVICE

I certify that on December 19, 2003, a true and correct copy of the foregoing Defendants' Motion For Leave To File A Response To Plaintiffs' Notice Of Filing Modified Amended Master Consolidated Class Action Complaint, Defendants' response to Notice of Filing Modified Amended Master Consolidated Class Action Complaint, and a Certification Pursuant to Local Rule 7.1 was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties.


Mark D. Smith

December 19, 2003